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| APPLICATION NO.                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------|-------------|----------------------|---------------------|------------------|
| 10/575,386                          | 04/07/2006  | Karlheinz Drauz      | 760188091           | 8990             |
| 66991                               | 7590        | 05/09/2008           |                     |                  |
| LAW OFFICE OF MICHAEL A. SANZO, LLC |             |                      | EXAMINER            |                  |
| 15400 CALHOUN DR.                   |             |                      | FRONDA, CHRISTIAN L |                  |
| SUITE 125                           |             |                      |                     |                  |
| ROCKVILLE, MD 20855                 |             |                      | ART UNIT            | PAPER NUMBER     |
|                                     |             |                      | 1652                |                  |
|                                     |             |                      | MAIL DATE           | DELIVERY MODE    |
|                                     |             |                      | 05/09/2008 PAPER    |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/575,386

**Applicant(s)**

DRAUZ ET AL.

**Examiner**

CHRISTIAN L. FRONDA

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 12-21 and 32-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-21 and 32-41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)  
Paper No(s)/Mail Date 8/10/07
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's election of Group I (claims 12-21 and new claims 32-41) without traverse in the reply filed on 02/08/2008 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.
2. Claims 12-21 and 32-41 are pending and under consideration in this Office Action.

#### *Claim Rejections - 35 U.S.C. § 112, 2nd Paragraph*

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 12-21 and 32-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the phrase "reacting a cyanide donor with an aldehyde or ketone" which renders the claim vague and indefinite. The metes and bounds of the claim are uncertain since the meaning of the phrase is not clearly defined or known. Furthermore, the claims are vague and indefinite because there are missing steps reciting production and isolation or recovery of the produced  $\alpha$ -hydroxycarboxylic acid or  $\alpha$ -hydroxycarboxylic amide. Dependent claims 13-21 and 32-41 are also rejected because they do not correct the defect of claim 12.

Similarly, claims 40 and 41 recite the phrase "cyanide donor is reacted with said aldehyde or ketone" renders the claim vague and indefinite. The metes and bounds of the claim are uncertain since the meaning of the phrase is not clearly defined or known.

Claim 17 recites the phrase "wherein said oxynitrilase is selected from the group consisting of *Sorghum bicolor*, *Hevea brasiliensis*, *Mannihot esculenta* and almond kernels" which renders the claim vague and indefinite. It is unclear if applicants actually intended to

Art Unit: 1652

recite that the oxynitrilase is obtained from these biological sources. Appropriate correction is requested.

*Claim Rejections - 35 U.S.C. § 103*

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

According to MPEP 2143:

“Exemplary rationales that may support a conclusion of obviousness include:

(A) Combining prior art elements according to known methods to yield predictable results;

(B) Simple substitution of one known element for another to obtain predictable results;

(C) Use of known technique to improve similar devices (methods, or products) in the same way;

(D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results;

(E) “Obvious to try” – choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success;

(F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art;

(G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Note that the list of rationales provided is not intended to be an all-inclusive list. Other rationales to support a conclusion of obviousness may be relied upon by Office personnel.”

6. Claims 12-21 and 32-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Griengl et al. (Trends in Biotechnology, Elsevier, Amsterdam, NL, vol. 18, no. 6, June 2000, pages 252-256; PTO 1449 from IDS filed 08/10/2007) in view of the combined teachings of

Art Unit: 1652

Nagasawa et al. (Eur J Biochem. 2000 Jan;267(1):138-44; PTO 892) and Osprian et al. (Journal of Molecular Catalysis B Enzymatic, vol. 24-25, 2003, pages 89-98; PTO 1449 from IDS filed 08/10/2007).

Griengl et al. teach a process for synthesis of enantiomerically pure and enriched cyanohydrins comprising contacting oxynitrilases with HCN (cyanide donor) and aldehydes or ketones, where the oxynitrilases are from biological sources such as *Sorghum bicolor*, *Hevea brasiliensis*, *Mannihot esculenta* and almond kernels. See entire publication especially pages 252-255 and Tables 1 and 2. The teachings of Griengl et al. differ from the claims in that a nitrilase or a nitrile hydratase is not used in the process.

Nagasawa et al. teach the nitrilase from *Rhodococcus rhodochrous* J1 which catalyzes the conversion of nitriles to their corresponding carboxylic acid. See entire publication especially pages 138-142 and Table 2.

Osprian et al. teach hydrolysis of cyanohydrins to enantiopure  $\alpha$ -hydroxycarboxylic acids using nitrile hydratase/amidase enzyme system present in *Rhodococcus erythropolis* NCIMB 11540. See entire publication especially pages 89-97 and Figs. 1-4.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Griengl et al. such that the nitrilase from *Rhodococcus rhodochrous* J1 taught by Nagasawa et al. and/or the nitrile hydratase/amidase enzyme system present in *Rhodococcus erythropolis* NCIMB 11540 taught by Osprian et al. are used with the oxynitrilase taught by Griengl et al. to predictably prepare enantiomer-enriched  $\alpha$ -hydroxycarboxylic acids or  $\alpha$ -hydroxycarboxylic amides from HCN and aldehydes or ketones as recited in claims 32-37. Further, it is within the purview of one of ordinary skill in the art to optimize the reaction conditions and temperature as recited in the claim 20 to have efficient production of large amounts of enantiomer-enriched  $\alpha$ -hydroxycarboxylic acids or  $\alpha$ -hydroxycarboxylic amides.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to have an efficient biocatalytic process to make enantiomer-

enriched  $\alpha$ -hydroxycarboxylic acids or  $\alpha$ -hydroxycarboxylic amides. One of ordinary skill in the art at the time the invention was made would have a reasonable expectation of success because the art of molecular biology and biocatalytic synthesis of compounds such as carboxylic acids and amides using enzymes are well known and developed.

Thus, the claimed invention was within the ordinary skill in the art to make and use at the time was made, and was as a whole *prima facie* obvious.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

### ***Conclusion***

7. No claim is allowed.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Thursday and alternate Fridays between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on (571)272-0934. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.
9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

Art Unit: 1652

applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christian L. Fronda/

Patent Examiner

Art Unit 1652